

### **Remarks/Arguments**

Claims 1 to 30 are pending. Claims 1, 10 and 27 have been amended.

The Office Action stated that the following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejection under this section made in the subject Office Action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 to 3, 10 to 13, 20, 25 and 26 have been rejected under 35 U.S.C. 102(b) as being anticipated by Bunin (4,911,304). Applicant traverses this rejection.

Independent Claims 1 and 10 have been amended so that the plastic film on the second side of the aluminum film is polychlorofluoroethylene (PCTFE). Bunin does not disclose PCTFE so Bunin does not anticipate any of the amended claims. Therefore, this anticipation rejection should be withdrawn.

The Office Action stated that, regarding Claims 1, 3, 10, 12, 13, 25 and 26, Bunin teaches a blister pack for tablets or similar article characterized by a 20 to 25 micron thick aluminum film (Column 2, line 33) which is uncoated one side and laminated (Column 2, lines 38 to 39) with a layer of 0.02 millimeters (20 microns) thick polyvinyl chloride (PVC) (Column 2, lines 38 and 39) on the other side. Bunin does not recite PCTFE so Bunin does not anticipate any of the amended claims.

The Office Action stated that, in general, the aluminum used for blister pack selected so as to be of suitable hardness to allow for the protection for the

enclosed tablets and soft enough to allow said tablets to be released when desired with reasonable applied pressure. Applicant traverses this statement. The term “reasonable applied pressure” would have to refer to peshing a hole in or the pill through the aluminum foil (as opposed to peeling the aluminum foil from over the blister). Bunin (Column 1, lines 49 to 55) says push through aluminum foil has a thickness in the range of about 0.02 or 0.04 millimeters.

The Office Action stated: that, regarding Claim 2, Bunin teaches the invention of Claim 1; and that Bunin does not mention the hardness state of the aluminum used in blister pack construction. Bunin does not teach the invention of amended Claim 1.

The Office Action stated that, in general, the aluminum used for blister pack selected so as to be of suitable hardness to allow for the protection for the enclosed tablets and soft enough to allow said tablets to be released when desired with reasonable applied pressure. As shown above, applicant has shown that this statement is incorrect.

The Office Action stated that, regarding Claim 11, Bunin teaches the invention of Claim 1. Bunin does not teach the invention of amended Claim 1.

The Office Action stated that Bunin also teaches that the plastics film (PVC) used for the plastic film portion of the blister pack (base) (Column 2, lines 18 and 19) is the same material (PVC) which is sealed (laminated) to the cover film (aluminum foil). This statement does not show anticipation of any of the amended claims.

The Office Action stated that, regarding Claim 20, Bunin teaches the invention of Claim 2. Bunin does not teach the invention of present Claim 2.

The Office Action stated that Bunin teaches a blister pack with an aluminum foil component having a thickness of 20 to 25 micron (Column 2, line 33). This statement does not show anticipation of any of applicant's present claims.

This rejection should be withdrawn.

Independent Claims 1 and 10 have each been amended to recite that the second side of the aluminum film is laminated with a polychlorotrifluoroethylene (PCTFE) film having a thickness of 8 to 76  $\mu\text{m}$ . (No other compounds of such plastic film are now recited in Claims 1 and 10.) Under the unity of invention principle for this national stage application (of the underlying PCT application), that should be guiding this national stage application, applicants (in effect) elect without traverse the independent and distinct invention where the plastic film laminated to the second side of the aluminum film that is polychlorotrifluoroethylene (PCTFE). Enclosed is a copy of applicant's European Patent No. EP 1617995 B1 (EP '995). Note that the English-language version of Claims 1 and 10 in EP '995 recite only polychlorotrifluoroethylene (PCTFE) in response to the unity of invention principle. In view of the unity of invention principle, the PVC of Bunin is an independent and distinct invention – so for this reason (among several other reasons) the PVC of Bunin is not an effective reference against applicant's (elected) amended claims.

Bunin discloses plastic films generically and more narrowly PVC, polyvinylidene chloride and fluoro plastics, Brunin does not disclose or suggest PCTFE. Applicant asserts that amended independent Claims 1 and 10 plus their dependent claims are not taught by Bunin or suggested by Bunin or Bunin and any of the cited secondary references.

Applicants understand the patents allowed in jurisdictions outside of the US are not controlling as to patentability because of different laws and standards as to patentability, but they should be given consideration in considering the US standards/requirements of patentability (e.g., obviousness).

Bunin and the cited secondary references are not very relevant to the newly amended claims.

The English-language translation of the International Preliminary Report On Patentability is already of record in the application. Reference is made to the pages thereof that discuss Invention 5, that is, the one directed to the use of PCTFE on the second side of the aluminum film. EP '995 is based upon elected Invention 5. (As an aside, note that such International Preliminary Report asserted that there were six inventions under the Unity Of Invention principle.) US Patent No. 5,560,490 (copy already submitted), (Chawla), that is, reference D10, is stated to be the closest of the cited references. It is stated that Chawla discloses a blister pack with a main body made of PCTFE at column 1, lines 62 to 67. EP '995 was patented over Chawla. New independent Claims 1 and 10, plus their dependent claims are novel and unobvious over Chawla. There is no teaching or suggestion in Chawla as to the use of a laminate with an aluminum

witm and a PCTFE film as a cover film for a blister pack (which is the subject matter of the amendments to independent Claims 1 and 10 herein).

The International Preliminary Report also cited US Patent No. 5,927,500 (copy already of record), (User et al.), that is, reference D11, is stated to disclose a blister pack with a main body made of PCTFE at column 3, lines 25 to 53. User et al also does not teach or suggest amended Claims 1 and 10 plus their dependent claims.

The Office Action stated: that the following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained through the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The Examiner has not resolved in the record the level of ordinary skill in the pertinent art as required by the Supreme Court's Graham and KSR decisions and the Patent Office's policy. With this mandatory factual resolution missing, all of the Section 103(a) rejections herein are defective and fail on this grounds alone. Without this mandatory resolution having been made by the Examiner, the Examiner has no basis for making any statement regarding one ordinarily skilled in the art.

Claims 19, 24 and 30 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Bunin (4,911,304). Applicant traverses this

statement.

Bunin does not teach or suggest the use of polychlorotrifluoroethylene (PCTFE) as the plastic film on the second side of the aluminum film of applicant's cover film. Hence, Bunin does not make any of applicant's present claims obvious.

The Office Action stated that, regarding Claim 19, Bunin teaches the invention of Claim 10. Bunin does not teach or suggest Claim 19. Bunin does not teach or suggest the use of PCTFE.

The Office Action stated: that Bunin teaches a blister pack for tablets or similar article characterized by a 20 to 25 micron thick aluminum film (Column 2, line 33) which is uncoated one side and laminated (Column 2, lines 38 to 39) with a layer of 0.02 millimeters (20 microns) thick polyvinyl chloride (PVC) (Column 2, lines 38 and 39) on the other side; that Bunin does not mention whether the plastic layer is applied with a paste method; and that Bunin uses the plastic film in the same manner as used by the applicant. This statement is not pertinent because Bunin does not teach or suggest the use of PCTFE.

The Office Action stated: that the portion of Claim 19 which requires "pasted" is considered to be a product-by-process limitation and is not given patentable weight; that "[e]ven though product-by-process claims are limited by and defined by the process, determination of the patentability is based on the product itself; that the patentability of the product does not depend on its method of production; that if the product in the product-by-process claim is the same as

or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process" *In re Thorpe*, 227 USPQ 964, 966); that once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product (*In re Marosi*, 710 F.2<sup>nd</sup>, 802, 218 USPQ 289, 292 (Fed. Cir. 1983, MPEP 2113). Applicant traverses this statement since the lower court decisions and the MPEP are not controlling because the Examiner has not done that which is necessary to make an obviousness rejection as per the Supreme Court decisions and the Patent Office's policy.

The Office Action stated that, regarding Claims 24 and 30, Bunin and Davie teach the invention of Claim 23. The combination of Bunin and Davie does not teach the invention of present Claim 23. Davie is not mentioned in the rejection statement so this rejection fails as being incomplete. The Office Action stated that Bunin and Machbitz teach the invention of Claim 29. The combination of Bunin and Machbitz does not teach the invention of present Claim 29. Machbitz is not mentioned in the rejection statement so this rejection fails as being incomplete.

The Office Action stated: that Bunin does not mention the coating method used to apply a plastic film on either side of the aluminum film; that Bunin teaches a blister pack for tablets or similar article characterized by a 20 to 25

micron thick aluminum film (Column 2, line 33) which is uncoated the first side and on the second side is laminated (Column 2, lines 38 to 39) with a plastic layer of 0.02 millimeters (20 microns) thick polyvinyl chloride (PVC) (Column 2, lines 38 and 39); and that Bunin uses a plastic film in the same fashion as the applicant to form a blaster pack. This statement does not teach or suggest the use of PCTFE.

The Office Action stated: that the portion of Claims 24 and 30 which requires "extrusion lamination" is considered to be a product-by-process limitation and if not given patentable weight; that "[e]ven though product-by-process claims are limited by and defined by the process, determination of the patentability is based on the product itself; that the patentability of the product does not depend on its method of production; that if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process" (*In re Thorpe*, 227 USPQ 964, 966); that once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product (*In re Marosi*, 710 F.2<sup>nd</sup>, 802, 218 USPQ 289, 292 (Fed. Cir. 1983, MPEP 2113). This statement is of no importance under Section 103(a) because the Examiner has not complied with the Supreme Court decisions and the Patent Office's policy as regards the mandatory determination of the substance matter discussed above.



This rejection should be withdrawn.

Claims 4, 5, 21 and 27 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Bunin (4,911,304) in view of Poore (4,254,871).

Applicant traverses this rejection.

The Examiner has not shown that Bunin and Poore can be combined under Section 103(a) in the search for applicant's claimed invention.

The Office Action stated: that, regarding Claim 4, Bunin teaches the invention of Claim 1. Bunin does not teach any of applicant's present claims.

The Office Action stated: that Bunin does not teach a blister pack comprising aluminum foil which on one side has been bonded to a protective lacquer layer; that Poore teaches a blister pack comprising aluminum film that one side is coated with a protective lacquer (Column 6, line 3); that Poore does not mention whether the lacquer is based on watery or organic solvents on the basis of nitrocellulose; and that it would have been obvious to someone of ordinary skill in the art at the time of the invention to use the protective lacquers used by Poore to prevent premature rupture of the aluminum film. Applicant traverses this statement. The Examiner cannot make any statement of what would be obvious to one ordinarily skilled in the art.

The Office Action stated: that Bunin and Poore disclose the claimed invention except for a lacquer based on watery or organic solvents on the basis of nitrocellulose; and that it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the appropriate protective lacquer, since it has been held to be within the general skill of a worker in the art

to select a known material (watery or organic solvents on the basis of nitrocellulose) on the basis of its suitability for the intended use as a matter of obvious choice (*In re Leshin*, 125 USPQ 416). Applicant traverses this statement. The Supreme Court decision trumps the lower court.

The Office Action stated: that, regarding 5, Bunin and Poore teach the invention of Claim 21. The combination of Bunin and Poore does not teach the invention of any of the present claims.

The Office Action stated: that Poore teaches that the one side of the blister pack aluminum film can be coated with a protective lacquer (Column 6, line 3); that Poore does not mention the coating weight of the protective lacquer; and that the lacquer used by Poore is used to protect the aluminum film in the same fashion as the applicant. This statement does not make any of the present claims obvious.

The Office Action stated: that it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the coating weight of the protective lacquer 0.5 to 5 g/m<sup>2</sup> for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art (*In re Boesch*, 617 F.2<sup>nd</sup> 272, 205 USPQ 215 (CCPA 1980)). Applicant traverses this statement. The lower court decision falls to the Supreme Court decisions. The Examiner also does not know what would be obvious to one ordinarily skilled in the art since the Examiner has not determined the level of ordinary skill in the art.

The Office Action stated that, regarding Claim 21, Bunin teaches the inventions of Claims 2 and 20. Bunin does not teach any of invention of any of the present claims.

The Office Action stated: that Bunin does not teach a blister pack comprising an aluminum foil which on one side has been coated with a protective lacquer; that Poore teaches that the one side of the blister pack aluminum film can be coated with a protective lacquer (Column 6, line 3); that Poore does not mention whether the lacquer is based on watery or organic solvents on the basis of nitrocellulose; and that the lacquer used by Poore is used to protect the aluminum film in the same fashion as the applicant. There is no showing that Bunin and Poore can be combined in the quest for applicant's claimed invention. The Examiner has not carried his burden of proof.

The Office Action stated: that Bunin and Poore disclose the claimed invention except for a lacquer based on watery or organic solvents on the basis of nitrocellulose; and that it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the appropriate protective lacquer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (*In re Leshin*, 125 USPQ 416). The Examiner does not know what would be obvious to one ordinarily skilled in the art.

The Office Action stated: that, regarding Claim 27, Bunin teaches the invention of Claim 26. Bunin does not teach the invention of the present claims.

The Office Action stated: that Bunin does not mention a blister pack wherein a protective lacquer layer is bonded to aluminum foil; that Poore teaches a blister pack pharmaceutical packages (Column 1, lines 1 to 5), characterized by a multilayer construction consisting of aluminum foil (sealing membrane) which is one side can have printing or protective lacquers (Column 5, lines 67 to 68; Column 6, lines 1 to 3); that Poore does not mention whether the protective lacquer layer is based on watery or organic solvents; and that Poore uses the protective lacquer layer in the same fashion as the applicant. This statement does not teach the invention of present Claim 27.

The Office Action stated: that Bunin and Poore disclose the claimed invention except for a lacquer based on watery or organic solvents on the basis of nitrocellulose; and that it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the appropriate protective lacquer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (*In re Leshin*, 125 USPQ 416). This statement is incorrect. The Supreme Court decisions control. The Examiner has not factually resolved the level of ordinary skill in the art.

This rejection should be withdrawn.

Claims 9, 14, 15 and 19 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Bunin (4,911,304) in view of Ludemann (6,006,913). Applicants traverse this rejection.

The Office Action stated that, regarding Claim 9, Bunin teaches the invention of Claim 1. Bunin does not teach the invention of present Claim 1.

The Office Action stated: that Bunin does not teach a blister pack comprising aluminum bonded to a protective lacquer layer; that Ludemann teaches a blister pack characterized by aluminum foil (push-through layer, Column 1, line 55) which on one side has been bonded to a protective layer (sealing layer) which includes PVC, polystyrene, styrene copolymers, polyester, and polyolefins (Column 3, lines 61 to 66); that Ludemann does not mention how the protective lacquer layer is bonded to the aluminum foil; and that Ludemann teaches that the protective layer ensures a permanent connection between the aluminum foil (push-through layer) and the packaging lower part (Column 3, lines 4 to 6). This statement does not make present Claim 9 obvious.

The Office Action stated that it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the protective layer of Ludemann with the unprotected aluminum taught by Bunin since Ludemann indicates that the issue related to low puncture resistance of the aluminum is decreased by the protective layer (Column 4, lines 45 to 47). The Examiner has no basis for stating what would be obvious to one ordinarily skilled in the art.

The Office Action stated: that the portion of Claim 9 which requires "extrusion lamination" is considered to be a product-by-process limitation and is not given patentable weight; that "even though product-by-process claims are limited by and defined by the process, determination of the patentability is based on the product itself; that the patentability of the product does not depend on its

method of production; that if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process" (*In re Thorpe*, 227 USPQ 964, 966); and that once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product (*In re Marosi*, 710 F.2<sup>nd</sup>, 802, 218 USPQ 289, 292 (Fed. Cir. 1983, MPEP 2113). The Supreme Court decisions control so this statement is of no importance under Section 103(a).

The Office Action stated that, regarding Claim 14, Bunin teaches the invention of Claims 10 and 26. Bunin does not teach the invention of present Claims 10 and 26.

The Office Action stated: that Bunin does not teach a blister pack comprising aluminum bonded to a protective lacquer layer; that Ludemann teaches a blister pack characterized by aluminum foil (push-through layer, Column 1, line 55) backing sheet (Column 1, lines 11 to 19) which on one side has been bonded to a protective lacquer layer (sealing layer) which can include PVC, polystyrene, styrene copolymers, polyester, and polyolefins (Column 3, lines 61 to 66); that Ludemann does not mention whether the protective lacquer is watery or organic solvent based; and that Ludemann uses the protective lacquer layer in the same fashion as the applicant. This statement does not teach or suggest any of the present claims.

The Office Action stated: that Bunin and Ludemann disclose the claimed invention except for a lacquer based on watery or organic solvents on the basis of nitrocellulose; that it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the appropriate protective lacquer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (*In re Leshin*, 125 USPQ 416); and that applicant should see also *Ballas Liquidating Co. v. Allied Industries of Kansas, Inc.* (DC Kans) 205 USPQ 331. This statement is incorrect. The Examiner has no basis for asserting would be obvious to one ordinarily skilled in the art. Also, the lower court decisions are preempted by the Supreme Court decisions.

The Office Action stated that, regarding Claim 15, Bunin and Ludemann teach the invention of Claim 14. The combination of Bunin and Ludemann does not teach the invention of present Claim 14. The Examiner has not shown that such references can be combined in the search for applicant's claimed invention. The combination of rejections does not result in applicant's claimed invention.

The Office Action stated: that Ludeman does not teach the coating weight of the protective (seal) layer; and that Ludemann uses similar protective layer material (polyester, Column 3, lines 61 to 66) in the same manner in the blister pack assembly as the applicant. This statement does not make any of applicant's present claims obvious.

The Office Action stated: that it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust coating weight of the

protective layer to 0.5 to 5g/m<sup>2</sup> for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art (*In re Böesch*, 617 F.2<sup>nd</sup> 272, 205 USPQ 215 (CCPA 1980)). Again the Examiner does not know what would be obvious to one ordinarily skilled in the art because the Examiner has not factually resolved the level of ordinary skill in the art.

The Office Action stated that, regarding Claim 19, Bunin teaches the invention of Claim 10. Bunin does not teach the invention of present Claim 10.

The Office Action stated: that Bunin does not teach a blister pack with a protective layer applied to the aluminum foil; that Ludemann teaches blister pack with a protective layer (sealing layer) which can be applied to the aluminum foil which include PVC, polystyrene, styrene copolymers, polyester, and polyolefins (Column 3, lines 61 to 66); and that Ludemann teaches that the sealing layer (protective layer) ensures a firm and permanent connection between the metal foil (push-through layer) layer and the packaging lower part (Column 3, lines 4 to 6). This statement does not teach or suggest applicant's claimed invention.

The Office Action stated: that the portion of Claim 19 which requires "pasted" is considered to be a product-by-process limitation and if not given patentable weight; that "[e]ven though product-by-process claims are limited by and defined by the process, determination of the patentability is based on the product itself; that the patentability of the product does not depend on its method of production; that if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though



the prior product was made by a different process” (*In re Thorpe*, 227 USPQ 964, 966); that once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product (*In re Marosi*, 710 F.2<sup>nd</sup> 802, 218 USPQ 289, 292 (Fed. Cir. 1983, MPEP 2113). This statement is of no weight under Section 103(a). The Supreme Court decisions and the Patent Office’s policy control (not the MPEP and the lower court decisions), and the Examiner has not made the mandatory factual resolution of the level of ordinary skill in the art, hence this statement is of no importance under Section 103(a).

This rejection should be withdrawn.

Claims 6 to 8 and 23 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Bunin (4,911,304) in view of Davie (4,125,190). Applicant traverse this rejection.

The Office Action stated that, regarding Claim 6, Bunin teaches the invention of Claim 1. Bunin does not teach the invention of present Claim 1.

The Office Action stated: that Bunin does not teach a blister pack that comprises an aluminum foil which on one side is bonded to a paper layer; that Davie teaches a blister pack (Column 1, lines 1 to 5) that comprises an aluminum foil which on one side is bonded to a paper layer; that Davie uses paper in essentially the same fashion as the applicant to protect the aluminum foil; that Davie does not give the type of paper used; that Davie teaches the aluminum

foils that are backed by a paper layer are considered to be more supported (Column 1, line 23); and that it would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the blister pack of Bunin with the blister pack of Davie utilizing aluminum bonded to a paper layer so that the articles in the blister pack can be better supported (Davie, Column 1, line 23). Applicant traverses this statement. This statement does not teach or suggest present Claim 6.

The Office Action stated: that Bunin and Davie disclose the claimed invention except for mentioning the type of paper used; and that it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the appropriate type of paper, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (*In re Leshin*, 125 USPQ 416). This statement is incorrect. The Examiner does not have any basis for asserting what would be obvious to one ordinary skilled in the art. Therefore, the lower court decision is meaningless in this rejection. The attempted combination of the two rejection references does not result in the present Claim 6.

The Office Action stated that, regarding Claim 7, Bunin and Davie teach the invention of Claim 6. The combination of Bunin and Davie does not result in the invention of present Claim 6.

The Office Action stated: that Bunin does not teach a blister pack that comprises an aluminum foil which on one side is bonded to a paper layer; that

Davie teaches a blister pack (Column 1, lines 1 to 5) that comprises an aluminum foil which on one side is bonded to a paper layer; that Davie uses paper in essentially the same fashion as the applicant to protect the aluminum foil; and that Davie does not give the weight of the paper layer. This statement does not teach or suggest and of the present claims.

The Office Action stated: that Bunin and Davie disclose the claimed invention except for disclosing the type of paper and the weight of the paper layer; that it would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the weight of the paper layer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (*In re Leshin*, 125 USPQ 416). The Examiner does not know what would be obvious to one ordinarily skilled in the art.

The Office Action stated that, regarding Claim 8, Bunin teaches the invention of Claim 1. Bunin does not teach the invention of amended Claim 1.

The Office Action stated: that Davie teaches a blister pack comprising an aluminum which on one side has bonded to a paper layer; that Davie does not mention how the paper layer is bonded to the aluminum foil; and that Davie used the paper layer in the same fashion as the applicant. This statement does not teach the invention of present Claim 8. Neither rejection reference teaches the use of PCTFE, for example.

The Office Action stated: that the portion of Claim 8 which requires “pasted” is considered to be a product-by-process limitation and is not given

patentable weight; that “even though product-by-process claims are limited by and defined by the process, determination of the patentability is based on the product itself[; that] the patentability of the product does not depend on its method of production[; that] if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process” (*In re Thorpe*, 227 USPQ 964, 966); and that once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product (*In re Marosi*, 710 F.2<sup>nd</sup> 802, 218 USPQ 289, 292 (Fed. Cir. 1983, MPEP 2113)). The Examiner still has the burden of proof and it has not shifted to the Examiner. The reason is that the lower court decisions and the MPEP are not controlling, and the Supreme Court decisions and Patent Office policy are controlling - they have not been followed in making these rejections, The substantive matter of factual resolution of the level of ordinary skill in the art is missing in the obviousness rejections.

The Office Action stated that, regarding Claim 23, Bunin teaches the invention of Claim 20. Bunin does not teach the invention of present Claim 20.

The Office Action stated: that Bunin does not teach a blister pack comprising an aluminum layer which on one side bonded to a protective paper or polyester film; and that Davie teaches a blister pack (Column 1, lines 1 to 5)

which comprises an aluminum foil which on one side is bonded to a paper layer (Column 1, line 22). This statement does not result in present Claim 23.

The Office Action stated that Davie does not mention whether the protective paper or polyester film is applied to the aluminum film based on a paste. The statement shows that this rejection does not support this obviousness rejection.

The Office Action stated: that the portion of Claim 23 which requires "pasted" is considered to be a product-by-process limitation and if not given patentable weight; that "[e]ven though product-by-process claims are limited by and defined by the process, determination of the patentability is based on the product itself; that the patentability of the product does not depend on its method of production; that, if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process" (*In re Thorpe*, 227 USPQ 964, 966); and that once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product (*In re Marosi*, 710 F.2<sup>nd</sup> 802, 218 USPQ 289, 292 (Fed. Cir. 1983, MPEP 2113). This statement is of no meaning under Section 103(a). The Examiner has destroyed this statement because the Examiner has not made the mandatory factual resolution. There is no shifting of the burden of proof.

This rejection should be withdrawn.

Claims 16 to 18, 22, 28 and 29 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Bunin (4,911,304) in view of over Machbitz (4,429,792). Applicant traverses this rejection.

The Office Action stated that, regarding Claims 16, 22 and 28, Bunin teaches the invention of Claims 10, 20 and 26. Bunin does not teach present Claims 10, 20 and 26.

The Office Action stated: that Bunin does not teach a blister pack wherein paper is adhered to the aluminum foil; that Machbitz teaches a blister pack with an aluminum foil bonded to a paper layer (Column 4, lines 32 to 33); that Machbitz does not mention the type of paper or the method by which the paper is applied in the blister pack construction; and that it would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the blister pack of Bunin with the coating of Machbitz, because the foil bonded to the paper layer is strong enough to withstand the stress imparted by an automatic printer and frangible enough so that pills can be ejected during use (Column 4, lines 37 to 40). This statement is in error and meaningless. The Examiner does not know what would be obvious to one ordinarily skilled in the art. The Examiner has not shown that one ordinarily skilled in the art would combine the two rejection references in the search for the claimed invention. The Examiner has not carried his burden of proof.

The Office Action stated that, regarding the coating weight, it would have been obvious to one having ordinary skill in the art at the time of the invention to

adjust the coating weight of for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2<sup>nd</sup> 272, 205 USPQ 215 (CCPA 1980). The Examiner does not know what would be obvious to one ordinarily skilled in the art so the rejection and this statement fail.

The Office Action stated that, regarding Claim 17, Bunin and Machbitz teach the invention of Claim 16. Bunin and Machbitz together, or solely, do not tech the invention of present Claim16.

The Office Action stated: that Machbitz teaches a blister pack with an aluminum foil bonded to a paper layer (Column 3, lines 26 to 33); and Machbitz does not mention the substance weight of the paper layer. This shows that present Claim 17 is unobvious.

The Office Action stated that it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the coating weight of the paper layer for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2<sup>nd</sup> 272, 205 USPQ 215 (CCPA 1980). The Examiner does not know what would be obvious to one ordinarily skilled in the art since the Examiner has not resolved the level of ordinary skill in the art.

The Office Action stated that, regarding Claim 18, Bunin teaches the invention of Claim 10. Bunin does not teach the invention of present Claim 10, and the Examiner has not proven otherwise.

The Office Action stated: that Bunin does not teach a blister pack comprising aluminum foil which on one side has been bonded to a paper or polyester film; that Machbitz teaches a blister pack with an aluminum foil which on one side is bonded to a paper layer (Column 3, lines 26 to 33); and that Machbitz does not mention whether the paper layer is bonded to the aluminum film on the basis of a paste. This shows the unobviousness of present Claim 18.

The Office Action stated: that the portion of Claim 18 which requires “pasted” is considered to be a product-by-process limitation and if not given patentable weight; that “[e]ven though product-by-process claims are limited by and defined by the process, determination of the patentability is based on the product itself; that the patentability of the product does not depend on its method of production; that, if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process” (*In re Thorpe*, 227 USPQ 964, 966); and that once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product (*In re Marosi*, 710 F.2<sup>nd</sup> 802, 218 USPQ 289, 292 (Fed. Cir. 1983, MPEP 2113). The burden of proof has not passed to the applicant. The Examiner still has the burden of proof.

The Office Action stated that, regarding Claim 29, Bunin teaches the invention of Claim 26. Bunin does not teach the present Claim 26.



The Office Action stated: that Bunin does not teach a blister pack wherein paper is adhered to the aluminum foil; that Machbitz teaches a blister pack with an aluminum foil bonded to a paper layer (Column 4, lines 32 to 33); that Machbitz teaches the use of a heat activated adhesive (Column 4, lines 30 and 31); that Machbitz does not mention whether the adhesive used to bond the paper layer to the aluminum film is watery, solvent based or solvent-free; and that Machbitz uses an adhesive to bond the paper layer to the aluminum in the same fashion as the applicant. This statement does not make applicant's present Claim 29 obvious.

The Office Action stated: that Bunin and Machbitz discloses the claimed invention except for mentioning whether the paper layer is applied by a watery, solvent-based or solvent-free medium; and that it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the appropriate medium of delivery for the paper layer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. This statement is incorrect on its face. What is within the general skill of a worker in the art is meaningless to what would be obvious to one ordinarily skilled in the art. The lower court decision is not in conformity with the Supreme Court decisions. There are no such controlling rules as set out in the lower court decision because it does not meet the mandatory framework of factual determinations required by the Supreme Court necessary to make an obviousness decision and before the secondary

consideration can be used. Also, the Examiner has not proven what is the general skill of a worker in the art [which actually has nothing to do with Section 103(a)],

The Office Action stated: that the portion of Claim 29 which requires “pasted” is considered to be a product-by-process limitation and if not given patentable weight; that “[e]ven though product-by-process claims are limited by and defined by the process, determination of the patentability is based on the product itself; that the patentability of the product does not depend on its method of production; that, if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process” (*In re Thorpe*, 227 USPQ 964, 966); that once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product (*In re Marosi*, 710 F.2<sup>nd</sup> 802, 218 USPQ 289, 292 (Fed. Cir. 1983, MPEP 2113). The burden of proof is still on the Examiner because the Examiner has not factually resolved in the record the level of ordinary skill in the art. The Examiner’s “rationale” is of no meaning until, and only until, the Examiner has made such factual resolution in the record. Even then it is meaningless because the Examiner has not proven that a process-by-product is involved or the selected is to be given no patentable weight. The Examiner position in such matter is clearly incorrect in fact and law. The

Examiner is requested to supply citation in the controlling Supreme Court decisions or the patent statute that supports his assertion.

In this matter, please note:

- (1) All words in a claim must be considered in judging the patentability of that claim against the prior art. In re Wilson, 165 USPQ 494, 496 (CCPA 1970).
- (2) To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 180 USPQ 580 (CCPA 1974).
- (3) If an independent claim is nonobvious under 35 U.S.C. 103, then any claim therefrom is nonobvious. In re Fine, 5 USPQ2d 1596 (Fed.Cir.).

Also please note that these citations come from MPEP 2143,03, Rev.5, Aug. 2006.

This rejection should be withdrawn.

Reconsideration, reexamination and allowance of the claims is requested.

Respectfully submitted,

February 3, 2009  
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**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on February 3, 2009,

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(11) **EP 1 617 995 B1**(12) **EUROPÄISCHE PATENTSCHRIFT**

(45) Veröffentlichungstag und Bekanntmachung des  
Hinweises auf die Patenterteilung:  
31.01.2007 Patentblatt 2007/05

(51) Int Cl.:

*B32B 15/08 (2006.01)**B32B 27/30 (2006.01)**B85D 75/36 (2006.01)**B32B 27/32 (2006.01)**B32B 27/35 (2006.01)*

(21) Anmeldenummer: 04725680.6

(86) Internationale Anmeldenummer:

PCT/EP2004/003583

(22) Anmeldetag: 05.04.2004

(87) Internationale Veröffentlichungsnummer:

WO 2004/091905 (28.10.2004 Gazette 2004/44)

(54) **DECKFOLIE FÜR BLISTERVERPACKUNGEN**

COVERING FOIL FOR BLISTER PACKS

OPERCULE DESTINEE A UN EMBALLAGE-COQUE

(84) Benannte Vertragsstaaten:  
AT BE BG CH CZ DE DK ES FR GB GR HU IE IT  
LI NL PL PT RO SE SI SK TR

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(30) Priorität: 16.04.2003 EP 03405269

(56) Entgegenhaltungen:

EP-A- 0 389 207

EP-A- 0 570 188

DE-A- 2 488 228

FR-A- 2 415 247

GB-A- 1 247 935

GB-A- 1 523 244

US-A- 3 332 549

US-A- 3 976 185

US-A- 4 867 986

US-A- 4 788 937

US-A- 5 580 490

US-A- 5 927 500

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Anmerkung: Innerhalb von neun Monaten nach der Bekanntmachung des Hinweises auf die Erteilung des europäischen Patents kann jedermann beim Europäischen Patentamt gegen das erteilte europäische Patent Einspruch einlegen. Der Einspruch ist schriftlich einzureichen und zu begründen. Er gilt erst als eingelegt, wenn die Einspruchsgebühr entrichtet worden ist. (Art. 99(1) Europäisches Patentübereinkommen).

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## Beschreibung

[0001] Die Erfindung betrifft eine Deckfolie für Blisterverpackungen mit thermo- oder kaltgeformten Blisterbodenteilen zur kindersicheren und seniorenfrendlichen Verpackung von pharmazeutischen Produkten.

[0002] Um die Anforderungen von Blisterpackungen an Kindersicherheit und Seniorenfrendlichkeit zu erfüllen, werden Deckfolien in der Form von Durchdrück-, Peel- und Peel-Push-Folien in Kombination mit entsprechenden Bodenfolien und Blisterdesign verwendet. Aufgrund unterschiedlicher gesetzgeberischer Vorschriften sind die in einem Land freigegebenen Blisterverpackungen in einem anderen Land nicht ohne weiteres ebenfalls zugelassen.

[0003] In den USA müssen alle Blisterverpackungen mit einem neuen Produkt, welches Kindersicherheit und Seniorenfrendlichkeit erfordert, in einem Praxistest geprüft werden. Ein entscheidendes Kriterium ist hier, dass die Kinder im Prüflatter aufgefordert werden, die Blisterpackung in den Mund zu nehmen und darauf zu beißen. Aus diesem Grund werden in den USA Verbundmaterialien mit der Schichtfolge Papier/PET/Aluminium/Heissiegeleischicht als Deckfolien eingesetzt. Da es kaum mehr möglich ist, diese Deckfolie zu durchbeißen, kann das Produkt im Blister aber auch nicht durch Herausdrücken aus der Packung entnommen werden. Die Deckfolie ist daher entweder als Peel- oder Peel-Push-Folie konzipiert oder die Blisterpackung ist vom Bodenteil her über Öffnungshilfen aufreissbar. Bedingt durch die beissfeste Ausgestaltung der Deckfolie weisen diese Blisterverpackungen notwendigerweise Kreuzperforationen und versteckte Öffnungshilfen auf. Dies führt zu einer wesentlichen Vergrößerung der Blister im Vergleich zu einer Durchdrückpackung mit einer üblichen Durchdrückfolie. Die Zunahme der Blisterdimensionen von mindestens 3 mm in der Breite und mindestens 12 mm in der Länge führt zu einer geringeren Flächenausbeute und damit zu einer Verkleinerung der Anzahl Blister pro Formtakt bei der Herstellung der Blisterpackungen.

[0004] Im Gegensatz zu den USA gibt es in Europa noch keine einheitlichen Vorschriften für kindersichere und seniorenfrendliche Blisterverpackungen. In Deutschland sind die nachstehenden Kombinationen von Deckfolien und Bodenteilen getestet und veröffentlicht worden:

Deckfolie	Bodenmaterial
50 g/m <sup>2</sup> Papier / 9 µm Al-Folie / 7 g/m <sup>2</sup> HSL (Heissiegelelack)	PVC, ACLAR® (PCTFE)
Purelay-ild (PE), 70-100 µm (Kreuzperforation)	PP
23 µm PET-Folie / Peelkleber / 20 µm Al-Folie / 5,6 g/m <sup>2</sup> HSL	PP, Formpack®-PP (A/PP)
40 g/m <sup>2</sup> Papier / 7 µm Al-Folie / 3,5 g/m <sup>2</sup> HSL	PP
Lack / 30 µm Al-Folie, hart, geprägt / 9 g/m <sup>2</sup> HSL	PVC
50 g/m <sup>2</sup> Papier / 9 µm Al-Folie / 7 g/m <sup>2</sup> HSL	PVC
35 g/m <sup>2</sup> Papier / 9 µm Al-Folie / 7 g/m <sup>2</sup> HSL	PVC
Lack / 25 µm Al-Folie / 9 g/m <sup>2</sup> HSL (Kreuzperforation)	PVC

[0005] Die Prüfung der Durchdrückelgenschaften erfolgt mechanisch. Hierbei wird mit einer definierten Geschwindigkeit ein halbrunder Stempel auf die in eine Halterung eingespannte Folieninnenseite gedrückt. Die zum Durchdrücken erforderliche Kraft wird in Newton angegeben.

[0006] Die nachstehenden, in vielen europäischen Ländern eingesetzten Ausführungen von Deckfolien weisen Durchdrückkräfte zwischen 38 und 58 N auf (Standardabweichung ca. 8):

Deckfolie	Durchdrückkraft [N]
50 g/m <sup>2</sup> Papier / 9 µm Al-Folie / 7 g/m <sup>2</sup> HSL	48
40 g/m <sup>2</sup> Papier / 7 µm Al-Folie / 3,5 g/m <sup>2</sup> HSL	41
Schutzlack / 30 µm Al-Folie, hart, geprägt / 9 g/m <sup>2</sup> HSL	58
35 g/m <sup>2</sup> Papier / 9 µm Al-Folie / 7 g/m <sup>2</sup> HSL	38
Schutzlack / 25 µm Al-Folie / 9 g/m <sup>2</sup> HSL (Kreuzperforation)	38

[0007] Im Gegensatz zu den in den USA geltenden Prüfverfahren müssen Verpackungen in Europa nur einmal nach obigem Verfahren geprüft werden und sind dann für alle Produkte generell als kindersicher zugelassen. Im Rahmen eines neuen Gesetzesentwurfs sind jedoch Bestrebungen im Gange, den in den USA obligatorischen Durchbeisstest

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auch in Europa als ein entscheidendes Kriterium für die Zulassung als kindersichere Verpackung in die Prüfung aufzunehmen. Dies würde für pharmazeutische Unternehmen bedeuten, dass neue Primärpackmittel verwendet werden müssen. Damit sind aber sehr kostenintensive Stabilitätsuntersuchungen verbunden, die Abpackanlagen müssen umgerüstet werden und die Produktivität bei der Blisterherstellung sinkt.

[0008] Aus US-A-5 927 600 und US-A-5 580 490 ist die Verwendung von Polychlortrifluorethylen (PCTFE) als Material einer Umverpackung für einen Blisterstreifen bzw. für ein Blisterbodenteil bekannt.

[0009] Der Erfindung liegt die Aufgabe zugrunde, eine zur Siegelung gegen alle gängigen Bodenmaterialien geeignete Deckfolie zu schaffen, die ein kindersicheres und seniorensicheres Öffnen von Blisterpackungen, einschliesslich Tropenblister, durch Durchdrücken ermöglicht und die auf bestehenden Abpackanlagen ohne Umrüsten eingesetzt werden kann.

[0010] Zur erfindungsgemässen Lösung der Aufgabe führen eine Deckfolie und eine Blisterverpackung mit den Merkmalen der unabhängigen Ansprüche 1 und 10.

[0011] Vorteilhafte Ausgestaltungen der Deckfolie und der Blisterverpackung sind Gegenstand von abhängigen Ansprüchen.

[0012] Das Material der zur Siegelung gegen das Blisterbodenteil vorgesehenen Kunststoffolie wird entsprechend dem Material der zur Siegelung vorgesehenen Seite des Blisterbodenteils gewählt. Damit ist die Kompatibilität der chemischen Struktur der mit dem Füllgut in Kontakt kommenden Seite der erfindungsgemässen Deckfolie mit der chemischen Struktur der mit dem Füllgut in Kontakt kommenden Seite einer bisher verwendeten und zugelassenen Bodenfolie sichergestellt, so dass die Durchführung neuer Stabilitätsuntersuchungen nicht zwingend erforderlich ist.

[0013] Die Fertigung der gewünschten Blisterverpackungen mit der erfindungsgemässen Deckfolie kann auf bestehenden Anlagen erfolgen.

[0014] Die Aluminiumfolie weist bevorzugt eine Dicke von 7 bis 30  $\mu\text{m}$  auf.

[0015] Bevorzugt besteht die Schutzlacksschicht auf der ersten Seite der Aluminiumfolie aus einem auf wässrigen oder organischen Lösungsmitteln basierenden Lack auf der Basis von Nitrozellulose, Epoxyharz, Harzstoffharz, Melaminharz, Polyester, Polyurethan oder von Abmischungen der genannten Lackrohstoffe, wobei das bevorzugte Auftragsgewicht der Schutzlacksschicht 0,5 bis 6  $\text{g}/\text{m}^2$  beträgt.

[0016] Das Papier auf der ersten Seite der Aluminiumfolie kann Pergaminpapier, Pergaminersatzpapier, gestrichenes oder satiniertes Papier mit einem bevorzugten Flächengewicht von 19 bis 60  $\text{g}/\text{m}^2$  sein.

[0017] Bevorzugt ist das Papier oder die Polyesterfolie auf der ersten Seite der Aluminiumfolie mit einem wässrigen, einem lösungsmittelbasierten oder einem lösungsmittelfreien Kaschiermittel gegen die Aluminiumfolie kaschiert.

[0018] Die Kunststoffolie auf der zweiten Seite der Aluminiumfolie kann mit einem wässrigen, einem lösungsmittelbasierten oder einem lösungsmittelfreien Kaschiermittel oder durch Extrusionskaschieren gegen die Aluminiumfolie kaschiert sein.

[0019] Bei einer Blisterverpackung mit einem Blisterbodenteil und einer gegen das Blisterbodenteil gesiegelten erfindungsgemässen Deckfolie besteht das Blisterbodenteil wenigstens auf der gegen die Deckfolie gesiegelten Seite aus einem Material, dessen chemische Struktur mit derjenigen der gegen das Blisterbodenteil gesiegelten Kunststoffolie kompatibel ist. Bevorzugt besteht das Blisterbodenteil wenigstens auf der gegen die Deckfolie gesiegelten Seite aus dem gleichen Material wie die gegen das Blisterbodenteil gesiegelte Kunststoffolie.

[0020] Beispiele von zur Herstellung von Blisterbodenteilen verwendeten Materialien sind Folien aus PVC, PVDC, PP, PET, PE und Verbundfolien wie PVC/ACLAR® (PCTFE), PVC/PVDC und COC oder FORMPACK® (Al-Al Blister).

[0021] Es sei hier noch erwähnt, dass sowohl die Deckfolie als auch die Bodenfolie bedruckt sein können.

[0022] In der nachstehenden Tabelle sind Beispiele von Deckfolien mit zugehöriger Durchdruckkraft zusammengestellt. Beispiel 1 ist eine erfindungsgemässe Deckfolie, die übrigen Beispiele sind nicht erfindungsgemässe Deckfolien. Mit "Beschichtung aussen" ist die nach aussen, mit "Beschichtung innen" die zur Siegelung gegen das Blisterbodenteil gerichtete Beschichtung der Aluminiumfolie bezeichnet, jeweils unter Angabe des Flächengewichts bei Lack- und bei Papierbeschichtung bzw. der Foliendicke bei Folienbeschichtung und der Verbindungsart zwischen der Beschichtung und der Aluminiumfolie.

Beispiel	Beschichtung aussen	Aluminium-folie	Beschichtung innen	Durchdruckkraft [N]
1	Schutzlack, 1,0 $\text{g}/\text{m}^2$ lackiert	20 $\mu\text{m}$ , hart	PVC-Folie, 15 $\mu\text{m}$ lackkaschiert	44
2	Schutzlack, 1,0 $\text{g}/\text{m}^2$ lackiert	25 $\mu\text{m}$ , weich	PVC-Folie, 25 $\mu\text{m}$ lackkaschiert	54
3	Papier, 21 $\text{g}/\text{m}^2$ kaschiert	20 $\mu\text{m}$ , hart 20 $\mu\text{m}$ , hart	PVC-Folie, 15 $\mu\text{m}$ lackkaschiert	59

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(fortgesetzt)

Beispiel	Beschichtung aussen	Aluminium-folie	Beschichtung innen	Durchdrückkraft [N]
4	Schutzlack, 1,0 g/m <sup>2</sup> lackiert	20 µm, hart	PVC-Folie, 25 µm lackkaschiert	61
5	Schutzlack, 1,0 g/m <sup>2</sup> lackiert	20 µm, hart	PVDC-Folie, 25 µm lackkaschiert	77
6	Schutzlack, 1,0 g/m <sup>2</sup> lackiert	20 µm, hart	PVC-Folie, 30 µm lackkaschiert	105
7	Schutzlack, 1,0 g/m <sup>2</sup> lackiert	20 µm, hart	PVC-Folie, 40 µm lackkaschiert	48
8	Schutzlack, 1,0 g/m <sup>2</sup> lackiert	20 µm, hart	ACLAR®-Folie, 15 µm lackkaschiert	76
9	PET-Folie, 7 µm kaschiert	9 µm, weich	PET-Folie, 7 µm kaschiert	94
10	Schutzlack, 1,0 g/m <sup>2</sup> lackiert	20 µm, hart	monoax. PP-Folie, 30 µm lackkaschiert	89
11	Schutzlack, 1,0 g/m <sup>2</sup> lackiert	20 µm, hart	monoax. PP-Folie, 20 µm extrusionskaschiert (7g/m <sup>2</sup> )	90
12	Schutzlack, 1,0 g/m <sup>2</sup> lackiert	25 µm, hart	monoax. PVC-Folie, 35 µm extrusionskaschiert (7g/m <sup>2</sup> )	48
13	Pergaminpapier, 35g/m <sup>2</sup> kaschiert	9 µm, weich	PVC-Folie, 15 µm lackkaschiert	20
14	Schutzlack, 1,0 g/m <sup>2</sup> lackiert	20 µm, hart	COC-Folie, 20 µm lackkaschiert	

## Patentansprüche

- Deckfolie für thermo- und kaltgeformte Blister zur kindersicheren und seniorenenfreundlichen Verpackung von Medikamenten und medizinischen Produkten, enthaltend eine 5 bis 30 µm dicke Aluminiumfolie, die auf einer ersten Seite a) unbeschichtet ist oder b) mit einem Schutzlack mit einem Auftragsgewicht von 0,1 bis 10 g/m<sup>2</sup> lackiert ist oder c) mit Papier mit einem Flächengewicht von 17 bis 80 g/m<sup>2</sup> kaschiert ist oder d) mit einer 5 bis 15 µm dicken Polyesterfolie kaschiert ist und auf der zweiten, zur Siegelung gegen ein Blisterbodenteil vorgesehenen Seite mit einer nicht, monoaxial oder biaxial gereckten Kunststofffolie auf der Basis von Polychlorotrifluorethylen (PCTFE) mit einer Follendicke von 8 bis 76 µm kaschiert ist.
- Deckfolie nach Anspruch 1, dadurch gekennzeichnet, dass die Aluminiumfolie im Zustand weich oder hart ist oder eine definierte Härte aufweist.
- Deckfolie nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass die Aluminiumfolie 7 bis 30 µm dick ist.
- Deckfolie nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, dass die Schutzlackschicht auf der ersten Seite der Aluminiumfolie aus einem auf wässrigen oder organischen Lösungsmitteln basierenden Lack auf der Basis von Nitrozellulose, Epoxyharz, Hamstoffharz, Melaminharz, Polyester, Polyurethan oder von Abmischungen der genannten Lackrohstoffe besteht.
- Deckfolie nach Anspruch 4, dadurch gekennzeichnet, dass das Auftragsgewicht der Schutzlackschicht 0,5 bis 5 g/m<sup>2</sup> beträgt.
- Deckfolie nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, dass das Papier auf der ersten Seite der



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Aluminiumfolie Pergaminpapier, Pergaminersatzpapier, gestrichenes oder satiniertes Papier ist.

7. Deckfolie nach Anspruch 6, dadurch gekennzeichnet, dass das Papier ein Flächengewicht von 19 bis 50 g/m<sup>2</sup> aufweist.
8. Deckfolie nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, dass das Papier oder die Polyesterfolie auf der ersten Seite der Aluminiumfolie mit einem wässrigen, einem Lösungsmittelbasierten oder einem lösungsmittelfreien Kaschiermittel gegen die Aluminiumfolie kaschiert ist.
9. Deckfolie nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, dass die Kunststoffolie auf der zweiten Seite der Aluminiumfolie mit einem wässrigen, einem Lösungsmittelbasierten oder einem lösungsmittelfreien Kaschiermittel oder durch Extrusionskaschieren gegen die Aluminiumfolie kaschiert ist.
10. Blisterverpackung mit einem Blisterbodenteil und einer gegen das Blisterbodenteil gesiegelten Deckfolie, wobei die Deckfolie eine 5 bis 30 µm dicke Aluminiumfolie ist, die auf einer ersten Seite a) unbeschichtet ist oder b) mit einem Schutzlack mit einem Auftragsgewicht von 0,1 bis 10 g/m<sup>2</sup> lackiert ist oder c) mit Papier mit einem Flächengewicht von 17 bis 60 g/m<sup>2</sup> kaschiert ist oder d) mit einer 5 bis 15 µm dicken Polyesterfolie kaschiert ist und auf der zweiten, gegen das Blisterbodenteil gesiegelten Seite mit einer nicht, monoaxial oder biaxial gereckten Kunststoffolie auf der Basis von Polychlorotrifluorethylen (PCTFE) mit einer Follendicke von 8 bis 78 µm kaschiert ist, und dass das Blisterbodenteil wenigstens auf der gegen die Deckfolie gesiegelten Seite aus einem Material besteht, dessen chemische Struktur mit derjenigen der gegen das Blisterbodenteil gesiegelten Kunststoffolie kompatibel ist.
11. Blisterverpackung nach Anspruch 10, dadurch gekennzeichnet, dass das Blisterbodenteil wenigstens auf der gegen die Deckfolie gesiegelten Seite aus dem gleichen Material besteht wie die gegen das Blisterbodenteil gesiegelte Kunststoffolie.
12. Blisterverpackung nach Anspruch 10 oder 11, dadurch gekennzeichnet, dass die Aluminiumfolie im Zustand weich oder hart ist oder eine definierte Härte aufweist.
13. Blisterverpackung nach einem der Ansprüche 10 bis 12, dadurch gekennzeichnet, dass die Aluminiumfolie 7 bis 30 µm dick ist.
14. Blisterverpackung nach einem der Ansprüche 10 bis 13, dadurch gekennzeichnet, dass die Schutzlackschicht auf der ersten Seite der Aluminiumfolie aus einem auf wässrigen oder organischen Lösungsmitteln basierenden Lack auf der Basis von Nitrozellulose, Epoxyharz, Harnstoffharz, Melaminharz, Polyester, Polyurethan oder von Abmischungen der genannten Lackrohstoffe besteht.
15. Blisterverpackung nach Anspruch 14, dadurch gekennzeichnet, dass das Auftragsgewicht der Schutzlackschicht 0,5 bis 5 g/m<sup>2</sup> beträgt.
16. Blisterverpackung nach einem der Ansprüche 10 bis 13, dadurch gekennzeichnet, dass das Papier auf der ersten Seite der Aluminiumfolie Pergaminpapier, Pergaminersatzpapier, gestrichenes oder satiniertes Papier ist.
17. Blisterverpackung nach Anspruch 16, dadurch gekennzeichnet, dass das Papier ein Flächengewicht von 19 bis 50 g/m<sup>2</sup> aufweist.
18. Blisterverpackung nach einem der Ansprüche 10 bis 13, dadurch gekennzeichnet, dass das Papier oder die Polyesterfolie auf der ersten Seite der Aluminiumfolie mit einem wässrigen, einem Lösungsmittelbasierten oder einem lösungsmittelfreien Kaschiermittel gegen die Aluminiumfolie kaschiert ist.
19. Blisterverpackung nach einem der Ansprüche 10 bis 18, dadurch gekennzeichnet, dass die Kunststoffolie auf der zweiten Seite der Aluminiumfolie mit einem wässrigen, einem Lösungsmittelbasierten oder einem lösungsmittelfreien Kaschiermittel oder durch Extrusionskaschieren gegen die Aluminiumfolie kaschiert ist.

## Claims

1. Covering foil for thermoformed and cold-formed blisters for the child-resistant and senior-friendly packaging of

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medicines and medicinal products, comprising a 5 to 30  $\mu\text{m}$  thick aluminium foil which on a first side a) is uncoated or b) is coated with a protective lacquer having a coating weight of 0.1 to 10  $\text{g}/\text{m}^2$  or c) is laminated with paper having a basis weight of 17 to 60  $\text{g}/\text{m}^2$  or d) is laminated with a 5 to 15  $\mu\text{m}$  thick polyester film and on the second side intended for sealing to a blister bottom part is laminated with a non-oriented, monoaxially oriented or biaxially oriented plastic film on the basis of polychlorotrifluoroethylene (PCTFE) having a film thickness of 8 to 76  $\mu\text{m}$ .

2. Covering foil according to claim 1, characterised in that the aluminium foil is in the soft or hard state or has a defined hardness.
3. Covering foil according to claim 1 or claim 2, characterised in that the aluminium foil is 7 to 30  $\mu\text{m}$  thick.
4. Covering foil according to one of claims 1 to 3, characterised in that the protective lacquer layer on the first side of the aluminium foil consists of a lacquer based on aqueous or organic solvents on the basis of nitrocellulose, epoxy resin, urea resin, melamine resin, polyester, polyurethane or mixtures of the said lacquer raw materials.
5. Covering foil according to claim 4, characterised in that the coating weight of the protective lacquer layer is 0.5 to 5  $\text{g}/\text{m}^2$ .
6. Covering foil according to one of claims 1 to 3, characterised in that the paper on the first side of the aluminium foil is glassine paper, parchment paper, coated paper or glazed paper.
7. Covering foil according to claim 6, characterised in that the paper has a basis weight of 18 to 50  $\text{g}/\text{m}^2$ .
8. Covering foil according to one of claims 1 to 3, characterised in that the paper or the polyester film on the first side of the aluminium foil is laminated to the aluminium foil by means of an aqueous, solvent-based or solvent-free laminating agent.
9. Covering foil according to one of claims 1 to 8, characterised in that the plastic film on the second side of the aluminium foil is laminated to the aluminium foil by means of an aqueous, solvent-based or solvent-free laminating agent or by extrusion lamination.
10. Blister pack comprising a blister bottom part and a covering foil sealed to the blister bottom part, the covering foil being a 5 to 30  $\mu\text{m}$  thick aluminium foil which on a first side a) is uncoated or b) is coated with a protective lacquer having a coating weight of 0.1 to 10  $\text{g}/\text{m}^2$  or c) is laminated with paper having a basis weight of 17 to 60  $\text{g}/\text{m}^2$  or d) is laminated with a 5 to 15  $\mu\text{m}$  thick polyester film and on the second side sealed to the blister bottom part is laminated with a non-oriented, monoaxially oriented or biaxially oriented plastic film on the basis of polychlorotrifluoroethylene (PCTFE) having a film thickness of 8 to 76  $\mu\text{m}$ , and that the blister bottom part consists at least on the side sealed to the covering foil of a material the chemical structure of which is compatible with that of the plastic film sealed to the blister bottom part.
11. Blister pack according to claim 10, characterised in that the blister bottom part consists at least on the side sealed to the covering foil of the same material as the plastic film sealed to the blister bottom part.
12. Blister pack according to claim 10 or claim 11, characterised in that the aluminium foil is in the soft or hard state or has a defined hardness.
13. Blister pack according to one of claims 10 to 12, characterised in that the aluminium foil is 7 to 30  $\mu\text{m}$  thick.
14. Blister pack according to one of claims 10 to 13, characterised in that the protective lacquer layer on the first side of the aluminium foil consists of a lacquer based on aqueous or organic solvents on the basis of nitrocellulose, epoxy resin, urea resin, melamine resin, polyester, polyurethane or mixtures of the said lacquer raw materials.
15. Blister pack according to claim 14, characterised in that the coating weight of the protective lacquer layer is 0.5 to 5  $\text{g}/\text{m}^2$ .
16. Blister pack according to one of claims 10 to 13, characterised in that the paper on the first side of the aluminium foil is glassine paper, parchment paper, coated paper or glazed paper.

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17. Blister pack according to claim 16, characterised in that the paper has a basis weight of 19 to 50 g/m<sup>2</sup>.
18. Blister pack according to one of claims 10 to 13, characterised in that the paper or the polyester film on the first side of the aluminium foil is laminated to the aluminium foil by means of an aqueous, solvent-based or solvent-free laminating agent.
19. Blister pack according to one of claims 10 to 18, characterised in that the plastic film on the second side of the aluminium foil is laminated to the aluminium foil by means of an aqueous, solvent-based or solvent-free laminating agent or by extrusion lamination.

## Revendications

1. Feuille de recouvrement pour emballages-coques thermoformés et formés à froid pour l'emballage conforme aux normes de sécurité pour enfants et convivial pour les seniors de médicaments et de produits médicaux, comprenant une feuille d'aluminium de 5 à 30  $\mu\text{m}$  d'épaisseur dont la première face est a) non recouverte ou b) est vernie avec un vernis de protection d'un poids d'application de 0,1 à 10 g/m<sup>2</sup> ou c) est contrecollée de papier d'un grammage de 17 à 60 g/m<sup>2</sup> ou d) est contrecollée d'une feuille de polyester de 5 à 15  $\mu\text{m}$  d'épaisseur et sur la deuxième face, prévue pour le scellement sur un fond d'emballage-coque, est recouverte d'une feuille en matière plastique non étirée, étirée selon un axe ou étirée selon deux axes à base de polychlorotrifluoroéthylène (PCTFE) d'une épaisseur de film de 8 à 78  $\mu\text{m}$ .
2. Feuille de recouvrement suivant la revendication 1, caractérisée en ce que la feuille d'aluminium est à l'état dur ou tendre ou présente une dureté définie.
3. Feuille de recouvrement suivant la revendication 1 ou 2, caractérisée en ce que la feuille d'aluminium a une épaisseur de 7 à 30  $\mu\text{m}$ .
4. Feuille de recouvrement suivant l'une des revendications 1 à 3, caractérisée en ce que la couche de vernis de protection sur la première face de la feuille d'aluminium est constituée d'un vernis à base d'eau ou de solvant organique à base de nitrocellulose, de résine époxy, de résine uréique, de résine de mélamine, de polyester, de polyuréthane ou de mélanges des matières premières des vernis cités.
5. Feuille de recouvrement suivant la revendication 4, caractérisée en ce que le poids d'application de la couche de vernis de protection est de 0,5 à 5 g/m<sup>2</sup>.
6. Feuille de recouvrement suivant l'une des revendications 1 à 3, caractérisée en ce que le papier sur la première face de la feuille d'aluminium est du papier parchemin, du papier parchemin imité, du papier couché ou du papier satiné.
7. Feuille de recouvrement suivant la revendication 6, caractérisée en ce que le papier présente un grammage de 19 à 50 g/m<sup>2</sup>.
8. Feuille de recouvrement suivant l'une des revendications 1 à 3, caractérisée en ce que le papier ou la feuille de polyester sur la première face de la feuille d'aluminium est contrecollé sur la feuille d'aluminium à l'aide d'un agent de contrecollage à base d'eau, de solvant ou sans solvant.
9. Feuille de recouvrement suivant l'une des revendications 1 à 8, caractérisée en ce que la feuille en matière plastique sur la deuxième face de la feuille d'aluminium est contrecollée sur la feuille d'aluminium à l'aide d'un agent de contrecollage à base d'eau, de solvant ou sans solvant ou par extrusion.
10. Emballage-coque avec un fond d'emballage-coque et une feuille de recouvrement scellée sur le fond d'emballage-coque, la feuille de recouvrement étant une feuille d'aluminium de 5 à 30  $\mu\text{m}$  d'épaisseur dont la première face est a) non recouverte ou b) est vernie avec un vernis de protection d'un poids d'application de 0,1 à 10 g/m<sup>2</sup> ou c) est contrecollée de papier d'un grammage de 17 à 60 g/m<sup>2</sup> ou d) est contrecollée d'une feuille de polyester de 5 à 15  $\mu\text{m}$  d'épaisseur et sur la deuxième face, scellée sur le fond d'emballage-coque, est recouverte d'une feuille en matière plastique non étirée, étirée selon un axe ou étirée selon deux axes à base de polychlorotrifluoroéthylène (PCTFE) d'une épaisseur de film de 8 à 78  $\mu\text{m}$ , et en ce que le fond d'emballage-coque est constitué au moins sur

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la face scellée sur la feuille de recouvrement d'un matériau dont structure chimique est compatible avec celle de la feuille en matière plastique scellée sur le fond d'emballage-coque.

5 11. Emballage-coque suivant la revendication 10, caractérisé en ce que le fond d'emballage-coque est constitué au moins sur la face scellée sur la feuille de recouvrement du même matériau que la feuille en matière plastique scellée sur le fond d'emballage-coque.

10 12. Emballage-coque suivant la revendication 10 ou 11, caractérisé en ce que la feuille d'aluminium est à l'état tendre ou dur ou présente une dureté définie.

13. Emballage-coque suivant l'une des revendications 10 à 12, caractérisé en ce que la feuille d'aluminium a une épaisseur de 7 à 30  $\mu\text{m}$ .

15 14. Emballage-coque suivant l'une des revendications 10 à 13, caractérisé en ce que la couche de vernis de protection sur la première face de la feuille d'aluminium est constituée d'un vernis à base d'eau ou de solvant organique à base de nitrocellulose, de résine époxy, de résine uréique, de résine de mélamine, de polyester, de polyuréthane ou de mélanges des matières premières des vernis cités.

20 15. Emballage-coque suivant la revendication 14, caractérisé en ce que le poids d'application de la couche de vernis de protection est de 0,5 à 5  $\text{g/m}^2$ .

16. Emballage-coque suivant l'une des revendications 10 à 13, caractérisé en ce que le papier sur la première face de la feuille d'aluminium est du papier parchemin, du papier parchemin imité, du papier couché ou du papier satiné.

25 17. Emballage-coque suivant la revendication 16, caractérisé en ce que le papier présente un grammage de 18 à 50  $\text{g/m}^2$ .

30 18. Emballage-coque suivant l'une des revendications 10 à 13, caractérisé en ce que le papier ou la feuille de polyester sur la première face de la feuille d'aluminium est contrecollé sur la feuille d'aluminium à l'aide d'un agent de contrecollage à base d'eau, de solvant ou sans solvant.

35 19. Emballage-coque suivant l'une des revendications 10 à 18, caractérisé en ce que la feuille en matière plastique sur la deuxième face de la feuille d'aluminium est contrecollée sur la feuille d'aluminium à l'aide d'un agent de contrecollage à base d'eau, de solvant ou sans solvant ou par extrusion.